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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,537	04/16/2001	Carl R. Merril	PNC-004	5407

7590 09/19/2005

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EXAMINER	
PRYOR, ALTON NATHANIEL	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/835,537	MERRIL ET AL.	
	Examiner	Art Unit	
	Alton N. Pryor	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,21-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19 and 21-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

I. Rejection of claims 1,2,7,9,10,15,19,20,23,24 under 35 USC 102(b) as being anticipated by Pocchairi will not be maintained. Urea has been deleted from the claims.

II. Rejection of claims 1-3,9,10,13-15,19-21,23,24,27-29 under 35 USC 102(b) as being anticipated by Manuelidis will not be maintained. Manuelidis does not disclose a method for treating instant prion disease but rather shows that prion protein is associated with a virus.

III. Rejection of claims 19,20,23,24 under 35 USC 102(b) will be maintained for reason on record and reason as follows. Goldin teaches insomnia broadly which encompasses fatal familial insomnia.

IV. Rejection of claim 8 under 35 USC 103(a) as being obvious over Pocchairi will not be maintained. Urea has been deleted from instant claims.

V. New Grounds of Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19,21-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for instant method of treating prion diseases listed in claim 23, specification does not reasonably provide enablement all other prior diseases. Also, the specification, while being enabling for instant method of treating prion diseases listed in claim 23 with guanidine HCl, the specification does not reasonably

provide enablement treating prior diseases using all other salts of guanidine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Because there exist many guanidine salts forms, these compounds would be of different sizes, polarity and electronegativity causing the activity of guanidine salts be questionable. The predictability in this art is high since a small change in a functional feature could result in a drastic change in activity and such a change can also result in an opposite effect or activity. To one of ordinary skill in the art, it would be a big job to determine the effect of all of the claimed structural changes. Because of this large burden (determination of which salts would render desired results), Examiner would like to point out that Applicant would be entitled to a subgenus of what is being claimed. Examiner stresses that the subgenus created should be a group of related salts based on the structure of the guanidine HCl in the specification. Examiner stresses that the subgenus created should be a group of related guanidine salts in terms of size, polarity and electronegativity. Size of a compound determines its ability to fit into the receptor site. Polarity and electronegativity determine binding interactions between the functionality of drug (compound) and the functionality of the drug receptor site. Both of these factors should be heavily considered in the election of a subgenus group of compounds for the instant invention. Also, based on Applicant's specification, Applicant is not entitled to all prion diseases. However, Applicant is entitled to the diseases listed in claim 23.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 19,22-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Kaddurah-Daouk et al (US20040054006 or 10/624785; 7/22/03). Kaddurah-Daouk teaches a method of administering guanidinoacetate (guanidine salt) to a mammal (human) in need of treatment of prion diseases such as Transmissible Spongiform Encephalopathy (TSE) diseases, scrapie, Bovine spongiform encephalopathy (BSE), Mad Cow Disease, Kuru, Gerstmann-Straussler-Scheinker disease (GSSD), Creutzfeldt-Jakob disease (CJD), new variant of CJD called vCJD. See page 2nd full paragraph and abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaddurah-Daouk as applied to claims 19,22-29 above. See 102(e) rejection above.

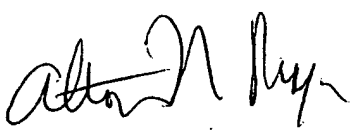
Kaddurah-Daouk teaches all that is recited in claim 30 except for the instant amount of guanidinoacetate being administered. It would have been obvious to one having ordinary skill in the art to determine the optimum amount of guanidioacetate to administer. One would have been motivated to do this in order to develop the most effective method for treating said prion diseases.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alton Pryor
Primary Examiner
AU 1616